K021462
p.1/2

JUN 6 2002

SECTION 5 – 510(k) SUMMARY

a. Submitted by

Arrow International, Inc.
9 Plymouth Street
Everett, MA 02149

Contact Person:

William Paquin
Quality Assurance / Regulatory Affairs Manager
Phone: (617) 389-6400 ext. 4345
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Date summary prepared: TBD

b. Device

Trade Name:	Intra-Aortic Balloon (IAB) with a Fiber Optic Sensor and Optic Measurement System
Common Name:	Intra-Aortic Balloon Catheter with a Fiber Optic Sensor and Measurement System
Classification Name:	Balloon, Intra-Aortic and Control System

c. Legally marketed devices to which substantial equivalence is claimed

The following table contains the predicate devices which we claim substantial equivalence.

Table 1: Predicate Devices

510(k)	Intra-Aortic Balloon Description
K000729	IAB 8Fr, 30cc Arrow Ultra 8
K000729	IAB 8Fr, 40cc Arrow Ultra 8
K963920	IAB 8Fr, 30cc Arrow NarrowFlex Universal
K993966	IAB 8Fr, 40cc Arrow NarrowFlex Universal
K981660	IAB 8Fr, 40cc RediGuard Arrow ArmorGlide

The fiber optic sensor and measurement system is technologically equivalent to the following device:

1. Camino Ventrix Subdural Tunneling Pressure Monitoring Kit from Camino NeuroCare, 5955 Pacific Center Blvd., San Diego, California 92121, Premarket Notification K982702.

00011

d. Description of device

IAB's are designed to provide cardiac assist therapy. In cardiac assist therapy a standard electronic pressure transducer can be connected externally to the central lumen of an IAB as a means of monitoring arterial pressure.

The purpose of the IAB device modification is to provide an alternative means for obtaining arterial pressure readings directly from the tip of the of an IAB catheter, as opposed to a standard electronic pressure transducer that is connected externally to the central lumen of an IAB.

A pressure sensor is attached to a flexible optical fiber in the IAB catheter. The sensor is positioned within the tip of the IAB catheter and the fiber runs the length of the inner lumen, exiting at the trifurcation and attaches to an optical connector. The sensor in the IAB catheter optically transmits light to a sensor measurement system. The sensor measurement system displays and outputs an arterial pressure.

Because the fiber optic sensor is positioned directly in the aorta, an arterial pressure can be directly obtained as opposed to obtaining arterial pressure readings through the end of a fluid-filled column and transducer. Additionally the fiber optic signal is optical not electrical, therefore, the pressure signal is immune to any electrical noise/interference that can affect a standard electronic pressure transducer. The fiber optic measurement system outputs the pressure via a digital or analog signal. The output signal can be input into a patient monitoring system or Intra-Aortic Balloon Pump (IABP).

e. Intended use of the device

The IAB is utilized for intra-aortic balloon counterpulsation therapy, whereby balloon inflation in the aorta during diastole and deflation during systole increase blood supply to the heart muscle and decrease work of the left ventricle.

f. Technological characteristics

The device has similar technological characteristics as previously cleared pressure sensors.

The results of the laboratory tests demonstrate that the device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 2002

Arrow International, Inc.
c/o Mr. William Paquin
Quality Assurance/Regulatory Affairs Manager
9 Plymouth Street
Everett, MA 02149

Re: K021462
Trade Name: Arrow Intra-Aortic Balloon Fiber Optic Sensor/Fiber Optic Sensor Measurement System
Regulation Number: 21 CFR 870.3535
Regulation Name: Balloon, Intra-Aortic and Control System
Regulatory Class: Class III (three)
Product Code: DSP
Dated: May 1, 2002
Received: May 7, 2002

Dear Mr. Paquin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

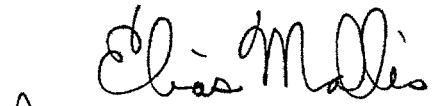
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ARROW INTERNATIONAL
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SECTION 6 – INDICATIONS FOR USE

Device Name: Arrow Intra-Aortic Balloon Fiber Optic Sensor/Fiber Optic Sensor Measurement System

- Refactory left ventricular failure
- Cardiogenic or septic shock
- Unstable refactory angina
- Impending angina
- Ischemia-related ventricular arrhythmias
- Weaning from cardiopulmonary bypass
- Support and stabilization during coronary angioplasty
- Intraoperative pulsatile flow generation
- Associated mechanical complications of acute myocardial infarction
- Support and stabilization of high-risk patients undergoing diagnostic and non-surgical procedures
- Mitral Valvuloplasty
- Bridge to Ventricular Assist Device
- Prophylactic support for cardiac surgery
- Post-surgical myocardial dysfunction
- Cardiac Contusion

Division of Cardiovascular & Respiratory Devices
510(k) Number K021462
Elias Mallis

Prescription Use ✓ K021462
(Per 21 CFR 801.109)